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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,436	08/21/2003	Martin Gleave	UBC.P-030	9171
21121	7590	07/22/2005	EXAMINER	
OPPEDAHL AND LARSON LLP P O BOX 5068 DILLON, CO 80435-5068			CHONG, KIMBERLY	
			ART UNIT	PAPER NUMBER
			1635	

DATE MAILED: 07/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/646,436	GLEAVE ET AL.	
	Examiner	Art Unit	
	Kimberly Chong	1635	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 10-14, 31 and 33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3 and 10-13 is/are rejected.
- 7) ☒ Claim(s) 4, 14, 31 and 33 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 August 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date <u>01/26/04, 3/18/04, 7/31/04, 8/18/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of Group I (claims 1-4, 10-14) and SEQ ID NO: 10 in the reply filed on 5/12/2005 is acknowledged.

It is noted that the requirement for restriction/election of a sequence (SEQ ID NO: 10 above) was not a requirement for election of a species, but rather a restriction/election because of an improper Markush.

Status of the Application

Claims 1-4, 10-14 and newly added claims 31 and 33 are currently under examination.

Priority

Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional applications upon which priority is claimed fail to provide adequate support under 35 U.S.C. 112 for claims 1-2, 4, 10-12, 14, 31 and 33 of this application.

The claims are drawn to an RNA molecule having a length of less than 49 bases and further wherein the RNA molecule has a length of 16 to 29 nucleotides in length.

The provisional applications 60/405,193, 60/408,152 and 60/472,387 disclose an RNA molecule 21 to 23 nucleotides in length. The above-mentioned applications fail to provide adequate support for RNA molecules less than 49 nucleotides in range but greater than 23 and further the applications fail to

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provide support for an RNA molecule less 21 nucleotides in length. If applicant feels there is adequate support then applicant must point out, with particularity, where such support can be found.

Therefore, claims 1-2, 4, 10-12, 14, 31 and 33 are given a priority date of 08/21/2003, the filing date of the instant application.

Claim Objections

Claims 4, 14, 31 and 33 are objected to as being dependent upon a rejected base claim, but would be allowable if applicant cancels non-elected subject matter and the claims are rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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Claims 1-2 and 10-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Monia et al. (US Patent No. 6,383,808).

Claim 1 is drawn to an RNA molecule having a length of less than 49 bases and further targeted to a gene that encodes clusterin. Claim 2 limits claim 1 by reciting the RNA molecule has a length of 16 to 29 nucleotides in length. Claims 10-12 are drawn to a pharmaceutical composition wherein the pharmaceutically acceptable carrier is a sterile injectable solution and comprising an RNA molecule having a length of less than 49 bases, 16 to 29 bases targeted to a gene that encodes clusterin.

Monia et al. teach an oligonucleotide that can be RNA or a ribozyme (see column 6, lines 37-63) that is targeted to clusterin mRNA (see Table 1). Monia et al. further teach the compounds are preferably from 12 to 30 nucleotides in length (see column 6, lines 54-59). Monia et al. teach a pharmaceutical composition comprising an RNA molecule and wherein the pharmaceutically acceptable carrier is a sterile injectable solution (see column 14, lines 4-10).

Thus, Monia et al. anticipates claims 1-2 and 10-12 of the instant application.

Claims 1-3 and 10-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Monia et al. (US Patent No. 6,383,808)

Claim 1 is drawn to an RNA molecule having a length of less than 49 bases and further targeted to a gene that encodes clusterin. Claims 2-3 limit claim 1 by reciting the RNA molecule has a length of 16 to 29 or 18 to 23

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nucleotides in length. Claims 10-13 are drawn to a pharmaceutical composition wherein the pharmaceutically acceptable carrier is a sterile injectable solution and comprising an RNA molecule having a length of less than 49 bases, 16 to 29 bases or 18 to 23 bases targeted to a gene that encodes clusterin.

Monia et al. teach an oligonucleotide that can be RNA or a ribozyme (see column 6, lines 37-63) and that is targeted to clusterin mRNA (see Table 1).

Monia et al. further teach the compounds are preferably from 12 to 30 nucleotides in length (see column 6, lines 54-59). Monia et al. teach a pharmaceutical composition comprising an RNA molecule and wherein the pharmaceutically acceptable carrier is a sterile injectable solution (see column 14, lines 4-10).

Thus, Monia et al. anticipates claims 1-3 and 10-13 of the instant application.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Friday between 7-4 pm.

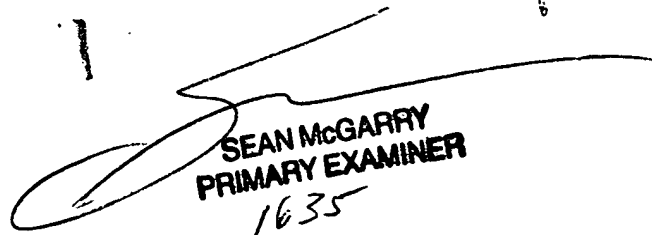
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached at 571-272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Kimberly Chong
Examiner
Art Unit 1635


SEAN MCGARRY
PRIMARY EXAMINER
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